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*Feb*

| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO.       |
|--|-------------|----------------------|------------------------------|------------------------|
| 09/842,466   | 04/26/2001  | Hiroyasu Kokubo      | 35576/233803                 | 8005                   |
| 826  | 7590        | 09/10/2007           |                              |                        |
| ALSTON & BIRD LLP<br>BANK OF AMERICA PLAZA<br>101 SOUTH TRYON STREET, SUITE 4000<br>CHARLOTTE, NC 28280-4000 |             |                      | EXAMINER<br>SHEIKH, HUMERA N |                        |
|  |             |                      | ART UNIT<br>1615             | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>09/10/2007      | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/842,466 | <b>Applicant(s)</b><br>KOKUBO ET AL. |  |
|                              | <b>Examiner</b><br>Humera N. Sheikh  | <b>Art Unit</b><br>1615              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-9, 11, 13-20 and 31-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9, 11, 13-20 and 31-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of the Application**

In view of the Appeal Brief filed 05/08/07, PROSECUTION IS HEREBY REOPENED.

Receipt of the Appeal Brief filed 05/08/07 is acknowledged.

Claims 6-9, 11, 13-20 and 31-47 are pending in this action. Claims 6-9, 11, 13-20 and 31-47 are rejected.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 6-9, 11, 13-20 and 31-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berta (U.S. Pat. No. 4,820,524) in view of**

**Berta ('524)** teaches a solid, multi-colored medicament preparation having a multi-colored gelatinous coating, wherein the coating layer provides two or more different colors (see reference col. 4, lines 5-42). The medicament may be in the form of a caplet and contains a layer of gelatin as a single coating on the caplet core (col. 4, lines 43-56).

Berta also teaches a method for coating the solid cores, such as caplets, to produce simulated, capsule-like medicaments. Berta teaches that one objective of the invention is to provide a simulated, capsule-like medicament having a gelatinous coating capable of being provided in two or more colors. Another objective is to provide a heavy layer of gelatin as a *single* coating to cover imperfections inherent on the caplet core (col. 4, lines 12-56). During the drying process, the caplet may be rotated to assist in uniformly distributing gelatin during drying (col. 5, lines 46-65). Suitable coatings to be used are gelatinous materials, such as methyl cellulose, calcium alginate and gelatin. Additional ingredients disclosed include plasticizers, preservatives, coloring agents and opacifying agents (col. 8, lines 20-47).

Berta teaches a solid, multi-colored medicament wherein colorings can be added to the coatings to produce opaque or transparent colors, such as red, white, pink, green, reddish brown, blue, yellow and black, for example. To form white medicaments or an opaque colored coating, titanium dioxide is often added to the gelatin (col. 9, lines 1-7). Berta teaches that first and second ends of the caplet can be coated with gelatinous coatings of different colors to provide a distinctive appearance for specialty products (col. 9, lines 3-5); (col. 10, lines 29-62). Berta teaches that the solid, multi-colored medicament preparation additionally comprises various coating patterns (see Figs. 8 a-d and col. 5, lines 28-29). Berta does not explicitly teach a logo, letters or a bar code on the medicament. However, the inclusion of logos, bar codes or letters, as

instantly claimed does not make the invention patentable since variations in designs or patterns in solid medicament forms is commonly and routinely practiced in the pharmaceutical art.

Berta teaches a solid preparation comprising a gelatinous coating that provides two or more colors wherein the medicament is smooth, shiny, multi-colored and has various coating patterns. These medicaments are pleasing to the eye, are easier to swallow than prior medicaments and offer a distinctive appearance, as similarly desired by the applicant.

Berta does not teach 'exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration'. However, this limitation does not impart a patentable distinction over the reference teachings of Berta. A product is being claimed in which the solid preparation comprises more than one distinct coloring agent. It is the position of the Examiner that the prior art expressly teaches a multi-colored, tablet formulation consisting of a first and second different coloring agents, wherein the tablet is provided with a single, multi-colored continuous coating layer. The instant claims are product claims and it is the patentability of the product that must be established, *per se*. Applicants have not demonstrated any unexpected or surprising results that accrue from the multi-colored, continuous film coating layer as claimed. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In this instance, the process of preparing the solid preparation does not afford patentable weight to the claims since Berta explicitly recognizes and teaches a solid medicament comprising a multi-colored, capsule-like coating, which is effective and aesthetically pleasing. The capsule-like medicaments have smooth, shiny, multi-colored gelatinous coatings thereon that are pleasing to the eye, easier to swallow and provide greater tamper resistance than conventional capsules.

In any event, **Hogan et al. ('738)** are relied upon for the teaching of a powder coating composition for electrostatic coating of pharmaceutical substrates. Hogan teaches electrostatic coating of cores of pharmaceutical tablets with a powder coating material, whereby treatment of the powder to form a film coating preferably involves a heating step, using infra red radiation as well as other forms of electromagnetic radiation (see column 1, lines 1-19); (col. 4, lines 32-35). Alternatively, the powder material may include a polymer which is cured during the treatment, for example by irradiation with energy in the gamma, ultraviolet or radio frequency bands, to form a cross-linked polymer film. The change in the powder material during treatment may be from a solid to liquid and then, on cooling, to a continuous solid film (col. 4, lines 35-44). The powder material includes a first component which forms a good continuous coat over the surface of the substrate (col. 7, line 61 – col. 8, line 16). Preferably the powder coating material further includes one or more colorants, for example, metal oxides or lakes (col. 9, lines 57-61). A different colored coating may be formed on each of the opposite faces of the tablet (col. 12, lines 30-44).

Hogan teaches fusing of the powder to provide for a uniform coating. The energy is provided by focused radiation (col. 16, lines 16-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the powder coating material methods of Hogan, which comprise the step of employing radiation, within the multi-colored tablet of Berta. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Hogan teaches that such a process would provide for a powder material having a good continuous coat over the surface of the substrate. The expected result would be an enhanced, multi-colored continuous coating layer having different colors along the body of the tablet for a pleasing colorful appearance for the consumer.

### ***Response to Arguments***

Applicant's arguments with respect to claims 6-9, 11, 13-20 and 31-47 have been considered but are moot in view of the new ground(s) of rejection.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh  
Primary Examiner

  
HUMERA N SHEIKH  
PRIMARY EXAMINER

Art Unit 1615

September 04, 2007

*hns*